Participant Information and Consent Form

Title	Managing Cancer and Living Meaningfully (CALM) in people with non-small cell lung cancer treated with novel therapies: A pilot study
Principal Investigator	Dr Fiona Lynch
Protocol Version	V3, 8th March 2022
Ethics Approval Number	21/245

1 Introduction

You are invited to take part in this project because you have been providing CALM sessions to people with lung cancer as part of the CALM pilot study that aims to assess the acceptability and feasibility of Managing Cancer and Living Meaningfully (CALM) with people with advanced lung cancer who have received immunotherapies or targeted therapies at Peter MacCallum Cancer Centre.

This form explains the project and what you will do if you decide to take part. Please read this information carefully. Please ask questions about anything you do not understand or want to know.

Your participation in this project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. Your decision to take part or not to take part in this project, or to take part and then withdraw, will not affect your relationship with the project staff. If you do not want to take part, but later change your mind, please contact the project team.

If you decide you want to take part in this project, you will be asked to provide verbal consent at the commencement of your interview. You will be given a copy of this form to keep.

2 What is the purpose of this project?

The purpose of this research is to understand the usefulness of the CALM therapy for people with advanced lung cancer who have been treated with novel therapies. CALM has been developed for people with advanced cancer but has not yet been assessed with people treated with novel therapies. We aim to get feedback from therapists about their experience delivering CALM to these patient participants.

This project is led by Dr Fiona Lynch, Clinical Psychologist at Peter Mac. The project is funded by a Peter Mac Cancer Foundation Grant.

3 What will I need to do if I am involved in this project?

If you choose to take part in this project, you will complete a once-off interview about your experience delivering the CALM therapy to these patient participants. This interview will be completed over the phone, over telehealth (video-call) or in person depending on your preference. This interview will last for approximately 30-45 minutes and be conducted by a member of the research team. This interview will be audio recorded and transcribed for analysis.

Other information: We will also ask you some short questions about your demographic background such as your years of experience, sex, and qualifications.

There are no costs associated with participating in this research project, nor will you be paid.

Should you wish to receive the overall results of this project you should inform the project team at the time of providing consent. We will send you these results at the end of the project.

4 What are the possible risks or disadvantages of taking part?

Lynch FA, *et al*. *BMJ Open* 2023; 13:e072322. doi: 10.1136/bmjopen-2023-072322

There are no anticipated risks associated with this project.

5 What if I withdraw from this project?

If you do consent to participate, you may withdraw at any time up until the completion of the project. If you decide to withdraw from the project, please notify a member of the research team.

You should be aware that data collected up to the time you withdraw will form part of the overall project results. If you do not want your data to be included, you must tell the project team member when you withdraw from the project. After completion of the project, your data will be included in the overall results and you will no longer be able to withdraw your data.

6 What will happen to information about me?

By signing the consent form, you consent to the project team collecting and using personal information about you for the evaluation of this project as described. We will keep this data in an unidentifiable format after the completion of the project to protect your privacy. The data will be stored on password protected computer files which will only be accessed by the project team.

Data will be stored for a period of seven (7) years and then will be confidentially destroyed.

The results of this project may be published or presented at seminars and conferences, but it will be done in a way that cannot identify you. Some journals will keep the overall de-identified data for an indefinite period.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the project team. You have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

7 Who has reviewed the project?

All research in Australia involving people is reviewed by an independent group of people that form a Human Research Ethics Committee (HREC). The ethical aspects of this project have been approved by the HREC of the Peter MacCallum Cancer Centre.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human intervention (research and non-research) studies.

8 Further information and who to contact

If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project (for example, feelings of distress), you can contact the Project Lead Fiona Lynch on 8559 8236 or any of the following people:

Project contact person	**Peter Mac complaints person**	**Peter Mac Ethics Committee**
Fiona Lynch	Position Consumer Liaison	Peter Mac Ethics Coordinator
Telephone: (03) 8559 8236	Telephone: (03) 8559 7517	Telephone: (03) 8559 7540
Email: fiona.lynch@petermac.org	Email: consumerliaison@petermac.org	Email: ethics@petermac.org

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Project and Ethics Approval Number	
Project Sponsor	Peter MacCallum Cancer Centre
Principal Investigator	Dr Fiona Lynch

Declaration by participant

- I have read the Participant Information and Consent Sheet or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the project.
- I have had an opportunity to ask questions about the project and what is required of me, and I am satisfied with the answers I have received.
- I freely agree to participate in this project as described and understand that I am free to withdraw at any time during the project without affecting my future care.
- I understand that I will be given a copy of this document to keep.

☐ Participant clearly states their agreement to participate

Declaration by Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

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